

**REMARKS**

Reconsideration and withdrawal of the rejections of the application are requested in view of these amendments and remarks, which place the application into condition for allowance.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1, 2, 8, 18-24 and 29-35 are pending in this application. Claims 1, 8, 18 and 29 are amended; claims 34 and 35 are added and read upon the elected embodiments. Support for the amendment to claim 1 can be found in cancelled claim 6. Support for the amendment to claim 29 can be found in cancelled claims 25-28. Support for new claim 34 can be found on page 48, lines 18-19. Support for new dependent claim 35 can be found, for example, on page 12, lines 17-19 and on page 13, lines 6-10. The amendment to the specification removes a URL. No new matter is added.

It is submitted that the claims are patentably distinct over the prior art and that these claims are and were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but simply for clarification and to round out the scope of protection to which Applicants are entitled.

**Claim Objections**

Claims 1, 3-5, 7-9 and 16 were objected to as allegedly reciting non-elected embodiments. Claim 1 is a linking claim and claim 8 recites an elected embodiment. The remaining claims are cancelled, obviating the objection.

The Office Action asserted that the claims of this application do not commence on a separate sheet in accordance with 37 CFR 1.52(b)(3). The Examiner is asked to review page 81 of the application as filed, which is entitled "CLAIMS" and begins with claim 1.

**Objections to the Specification**

The disclosure was objected to as recited hyperlinks. The specification was amended accordingly.

The disclosure was also objected to as allegedly not reciting sequence identifiers on pages 66-70 and in the Brief Description of Drawings. The Examiner's attention is directed to the Amendment filed on June 28, 2004, which inserted sequence identifiers into the appropriate places in the application.

## Information Disclosure Statement

Applicants' representative is aware of the rules regarding information disclosure statements. To the extent that any of the references listed on pages 78-80 are material to patentability, they are cited in information disclosure statements. Otherwise, these references are intended to provide the reader with background and supplemental information that is not required for patentability.

## **II. THE REJECTIONS UNDER 35 U.S.C. § 112 ARE OVERCOME**

Claims 1-5, 7-9, 16-24, 29 and 31 were rejected under the first paragraph of Section 112 as allegedly lacking enablement. The rejection is traversed.

The invention is directed to a conjugate comprising (i) a protein that binds to an APC and (ii) a Notch ligand sequence. Example 1 of the specification teaches how to make this conjugate. Moreover, one of skill in the art would know how to use this conjugate because, as the Examiner alludes in the paragraph bridging pages 12 and 13 of the Office Action, upon binding Notch, a "Notch ligand which retains signalling activity" (as specified in amended claim 1) "inherently upregulates" Notch activity.

The terms "modulates," "analog," and "derived from" are no longer recited in the claims. Therefore, any rejection based on such language is moot.

Moreover, which sequences bind to an APC is not, as the Office Action alleges on page 7, unpredictable. To the contrary, several of such molecules are described in the specification, for example, at page 13, lines 5-21, such as antibodies to CD205 (DEC205), CD204, CD14, CD206, TLRs, Langerin (CD207), DC-SIGN (CD209), CD32, CD68, CD83, CD33, CD54 or BDCA-2,3,4. In addition, conventional protein binding assays can be used to determine whether a sequence binds to an APC. Such assays are well within the ordinary skill of the artisan and do not constitute undue experimentation.

Claims 1-5, 7-9, 16-24, 29 and 31 were rejected under the first paragraph of Section 112 as allegedly lacking adequate written description. The rejection is traversed.

As discussed above, the genus of APC-binding molecules is defined and was possessed by the Applicants at the time of filing. Likewise, a Notch ligand or fragment retaining Notch signaling activity is known to the skilled artisan. One example of a Notch ligand fragment that retains Notch signaling activity is that claimed in claim 34. The nature of Notch ligands is discussed extensively in the application beginning on page 48, line 26. The DSL domain,

characteristic of Notch ligands, is discussed beginning on page 50, line 41. Therefore, written description exists for the full range of species encompassed by the claimed genus.

The other issues raised by the Examiner regarding written description have been cured by the amendments to the claims.

Claim 8 was rejected under the second paragraph of Section 112 as allegedly being indefinite. Claim 8 has been amended for clarity and to specify for avoidance of any doubt that "Delta" and "Serrate" are Notch ligand proteins.

### **III. THE REJECTIONS UNDER 35 U.S.C. § 102 ARE OVERCOME**

Claims 1-4, 16-20, 22-24, 29 and 31 were rejected under Section 102(b) as allegedly being anticipated by U.S. Patent No. 5,716,623 ("the '623 patent") and WO 98/26747 and under Section 102(e) as allegedly being anticipated by U.S. Patent No. 6,340,461 ("the '461 patent"). Claims 1-4, 16-24 and 31 were rejected under Section 102(e) as allegedly being anticipated by U.S. Patent No. 6,514,498. None of the cited references teach a conjugate that includes a Notch ligand sequence, as required by amended claim 1 and new claim 34. Therefore, the references do not teach every element of the present claims and cannot anticipate the claims.

Claims 1, 2, 5, 7-9, 19 and 31 were rejected under Section 102(b) as allegedly being anticipated by U.S. Patent No. 6,004,924 ("the '924 patent"). However, the '924 patent makes no reference to binding to an APC, as required by the present claims. A species is not necessarily anticipated by a genus that does not name the species or provide teachings that would lead one of skill in the art to the species. (See MPEP 2131.02.)

Reconsideration and withdrawal of the anticipation rejections are requested.

Respectfully submitted,

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